UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,454	06/20/2005	Yongfeng Wang	16188.0001U1	8104

23859 7590 04/08/2009

Ballard Spahr Andrews & Ingersoll, LLP
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,454	WANG ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Remarks dated 1/6/09.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragab (WO 00/57867 hereafter '867). The claims are drawn to a controlled release formulation comprising temozolomide.

The '867 patent teaches a sustained release temozolomide formulation comprising at least 3.3% (page 4). Regarding the "implantable" limitation it is the position of the Examiner that the disclosures of the prior art anticipates the instant claims since the limitation is merely a future intended use. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ragab (WO 00/57867 hereafter '867) in view of Gopferick (USPN 6,086,908 hereafter '908). The claims are drawn to a controlled release formulation comprising a polyanhydride combination. The claims also recite a method of making the formulation.

As discussed above the '867 patent discloses a controlled release formulation comprising temozolomide and controlled release polymers. The reference is silent to the specific polyanhydride of the instant claims, however these polymers are well known in the controlled release arts. This can be seen in the '908 patent.

The '908 patent discloses an implant tablet for sustained release comprising 3, 4-bis (p-carboxyphenoxy) propane (CPP) and sebacic acid in a ratio of 20:80 (examples). The reference discloses a method of making the tablets comprising dissolving the polymers in an appropriate solvent, dispersing a drug into the dissolved polymer, forming particles of the polymer/drug combination by evaporating the solvent, and compressing these particles into a tablet (col. 2, lin. 55-col. 3, lin. 20). The reference silent to spray-drying the dissolved polymer formulation in order to arrive at the microparticles, however the process of the '908 patent result sin the same

controlled release implantable tablet as the instant claims. Particles of a dispersed active agent and polymer are formed, and then further compressed into a tablet. Since the result of the process steps is the same formulation it is the position of the Examiner that the disclosures of the prior art obviate the instant claims.

With these things in mind it would have been obvious to combine the cancer agents of the '867 patent into the formulation of the '908 patent in order to provide a stable long term implantable device. One of ordinary skill in the art would have been motivated to combine the teachings and suggestions of the art as such with an expected result of a stable drug formulation useful in providing sustained cancer treating relief.

Claims 7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ragab (WO 00/57867 hereafter '867) in view of Gopferick (USPN 6,086,908 hereafter '908) and Sjoblom (USPN 6,753,014 hereafter '014). The claims are drawn to a process for making a controlled release tablet comprising dispersing the drug in a dissolve polymer, forming particles from this mixture by ultrasonic emulsifying, forming microspheres and tableting the resulting spheres.

As discussed above the '867 patent and the '908 patent provide a method of making controlled release tablets comprising temozolomide and CPP-SA-20:80 polymers by dispersing the drug into the polymer, forming particles and compressing the particles into a tablet. The combination is silent to the formation of particles via an emulsifying process, or the specific solvent used to form the polymer solution. The formation of microparticles from an emulsion is well known in the art as well as an appropriate solvent for CPP-SA 20:80, these elements are taught by the '014 patent.

The ‘014 patent discloses a method of making stable sustained release tablet comprising forming particles of dispersed drug compounds and polymers, and compressing the particles into stable tablets (abstract). First solutions of polymeric materials are formed by dissolving the mixing in a solvent such as methyl chloride (claim 14); next active agents are combined with the solution before it is emulsified through an ultrasonic nozzle (col. 5, lin. 19-35). The emulsion can be mixed with other polymers before the solvent is removed and microspheres are formed (col. 5, lin. 50-col. 6, lin. 30). The microspheres compressed into a tablet (col. 7, lin. 25-30). It would have been obvious to use the method of the ‘014 patent since many of the polymeric materials are similar to hose of the ‘908 patent.

With these things in mind it would have been obvious to combine the teachings and suggestions of the prior art with an expected result of the stable controlled release tablet. The artisan would have been motivated to use the method of the’014 patent in order to protect the anti cancer agents of the ‘867 patent from excessive heat. One of ordinary skill in the art would have been motivated to combine these disclosures with an expected result of a stable long term ant-cancer formulation.

Response to Arguments

Applicant's arguments filed 1/6/09 have been fully considered but they are not persuasive. Applicant argues that:

> The ‘867 patent does no teach the controlled release system of the instant claims.
>
> The combination of the ‘867, ‘908 and the ‘014 are not obvious since there is no motivation to combine the art since the '867 patent does not disclose the controlled release formulation of the instant claims.

Regarding the first argument, it remains the position of the Examiner that the '867 patent continues to teach the claimed controlled release formulation. The '867 patent teaches a controlled release formulation comprising 3.3% temozolomide and sodium starch glycolate, a biodegradable polymeric material (page 4). The formulation can take the form of a suppository, an implantable device (page 4). Applicant argues that the '867 does not teach a sustained release formulation, however the claims are drawn to a controlled release formulation and NOT a sustained release formulation. Even if a sustained release formulation was claimed, this limitation would merely be a future intended use and not impart patentability on the claims in view of the structurally complete '867 patent. Applicant argues that the capsule of the '867 patent is different from that of the instant claims yet provides no distinctions. The claims merely recite a controlled release formulation comprising 3-10 % of the drug and a biodegradable polymeric material. The '867 patent discloses the same drug, combined with biodegradable polymeric materials, and as such fully anticipates the instant claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the extended 12 hour controlled release of the invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically the claims are merely drawn to a controlled release formulation comprising biodegradable polymers. The '867 patent provides a controlled release formulation comprising the same concentration of active agent in combination with biodegradable polymers. The claims nowhere recite the length of administration or the number of administrations. These features are

not claimed and thus are irrelevant to the patentability in view of the prior art. The combination of the '867 and the '908 patent provide the same drug and biodegradable polymeric materials. The '867 patent provides the drug while the '908 patent provides the specific controlled release formulation comprising 3, 4-bis (p-carboxyphenoxy) propane (CPP) and sebacic acid in a ratio of 20:80. As such any inherent controlled release profile would also be present in the combination. The '010 patent merely provides the processing step of the additional solvent. While solvents are suggested in the '867 and '908 patent, the specific solvent is taught in the '010 patent. A simple substitution of these ingredients would have been obvious since each patent is concerned with making controlled release formulations. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618